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5. 510(k) Summary

[As required by 21 CFR 807.92]

FEB 27 2009

Submitted by	ProTron Technologies, LLC 141 Oakdene Ave Leonia, NJ 07605 Phone 201.297.7377
Contact person	Leon M. Dondysh
Date Prepared	December 20, 2008
Device trade name	ProTron Technologies, LLC, Electronic Stethoscope Model: Stethotron
Common name	Electronic Stethoscope
Classification name	Stethoscope; 21 CFR Sec. 870.1875(b) Electronic stethoscope, Product code DQD Class II

Intended Use

The ProTron Technologies, Electronic Stethoscope, Model Stethotron is intended for medical diagnostic purpose only. Stethotron has two modes of operation, amplification with filtering (Mode 1) and amplification only (Mode 2). Mode 1 filters out sounds below 350 Hz and above 1,000 Hz and used to listen specifically for vascular pathology. Mode 2 is used to listen for heart, lung, arteries, and other body sounds from 20 Hz to 20,000 Hz during routine physical examinations. Stethotron can be used on adult or paediatric patients undergoing physical examination.

Predicate Device to which Substantial Equivalence is Claimed

The ProTron Technologies, LLC Electronic Stethoscope, Model Stethotron is substantial equivalent to the 3M Littman Electronic Stethoscope, Model 2000 cleared for market under Premarket Notification k961848.

Summary of how the differences in technological characteristic compare to the predicate device [807.92(a)(6)]:

ProTron Technologies, LLC Electronic Stethoscope, Model Stethotron	3M Littman Electronic Stethoscope, Model 2000	Discussion
Two AAA alkaline batteries (maximum 1.5 volts)	One AAA alkaline battery (Maximum 3 volts)	A 1.5 volt increase in power does not materially effect the use or safety of the device
Two modes of operation, Mode 1 amplifies the range from 350 Hz to 1,000 Hz; Mode 2 amplifies the full range, 20 Hz to 20,000 Hz	Three frequency response modes to choose from: Bell (20-200 Hz), Diaphragm (100-500 Hz) and Extended Range (20-1,000 Hz).	Sounds from 20-1,000 Hz can be amplified with both devices. The collection of sounds in Mode 2 from 1-50 Hz does not significantly alter the effectiveness of the device.
No automatic shutoff	Automatic shutoff	Automatic shutoff only serves to prolong battery life and does not significantly alter the effectiveness or safety of the device.

Description of Device

The ProTron Technologies, LLC Electronic Stethoscope, Model Stethotron is a battery powered analog diagnostic device with two user selectable modes of operation for detecting, amplifying and filtering sounds of the heart, lungs, arteries, and internal organs. Mode 1 provides amplification and filters out sounds below 350 Hz and above 1,000 Hz. Mode 2 provides amplification only, 20 Hz to 20,000 Hz. Stethotron has volume controls on both filtrated and non-filtrated sounds enabling the user adjust the sound to the level desired. The chestpiece of the device is sized for use with adult or pediatric patients and is a bell and diaphragm design incorporating a microphone. All electronics are contained in a plastic electronics casing positioned below the bifurcation of the stethoscope yoke that connects to the headset that terminates at the eartips. The electronic casing includes the ON/OFF switch, volume control, and mode of operation selection control on the face. It contains the amplification and filtering electronics, a speaker and batteries. Stethotron has no software and is powered by two AAA alkaline batteries.

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Test Data

Test data includes electrical testing demonstrating the The ProTron Technologies, LLC Electronic Stethoscope, Model Stethotron to be safe and effective under label conditions.

Non-clinical Testing Brief Description:

Testing to determine response and gain are equivalent to the predicate electronic stethoscope was preformed with a computerized audio analysis system sweeps a frequency oscillator from 20 to 10,000 Hz. This frequency sweep is presented to a transducer on which the stethoscope is placed. The computer measures the response from the stethoscope with a small calibrated microphone placed in the eartip. The signal from the microphone is fed back to the computer where it is recorded, stored, and can be printed. The test was done in each of the two amplification modes, filtered and non-filtered.

Biocompatability

All components of the Electronic Stethoscope, Model "Stethotron" have been reviewed for biocompatibility. With respect to ISO 10993-Part 1 Biological Evaluation of Medical Devices for limited (<24 hour) skin contact for both patient and/or health care professional exposure. Each component with potential skin contact with either the user or patient was reviewed for possible health concerns. ProTron Technologies Company concludes that all of the components of the Electronic Stethoscope, Model "Stethotron" that make skin contact would have no potential for adverse health concern, all materials have a demonstrable history of use in a specified role that is equivalent to this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2009

ProTron Technologies, LLC
c/o Mr. Leon M. Dondysh
141 Oakdene Avenue
Leonia, NJ 07605

Re: K082771
Trade Name: Electronic Stethoscope Model Stethotron
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: January 9, 2009
Received: January 13, 2009

Dear Mr. Dondysh:

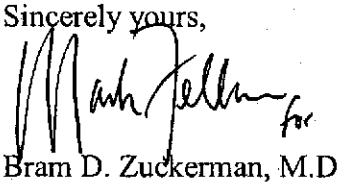
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082771

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K082771

Device Name: ProTron Technologies, LLC Electronic Stethoscope, Model Stethotron

Indications for Use:

The ProTron Technologies, Electronic Stethoscope, Model Stethotron is intended for medical diagnostic purpose only. Stethotron has two modes of operation, amplification with filtering (Mode 1) and amplification only (Mode 2). Mode 1 filters out sounds below 350 Hz and above 1,000 Hz and used to listen specifically for vascular pathology. Mode 2 is used to listen for heart, lung, arteries, and other body sounds from 20 Hz to 20,000 Hz during routine physical examinations. Stethotron can be used on adult or paediatric patients undergoing physical examination.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082771

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